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PATENT & TRADEMARK OFFICE

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Ekaterina Dadachova, Joshua D. Nosanchuk, and Arturo Casadevall
Appl. No.	:	10/775,869
Filed	:	February 10, 2004
For	:	RADIOLABELED ANTIBODIES FOR TREATMENT OF TUMORS
Group Art	:	1642
Examiner	:	Brandon J. Fetterolf
Customer No.	:	1912

DECLARATION OF EKATERINA DADACHOVA UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Ekaterina Dadachova, hereby declare as follows:

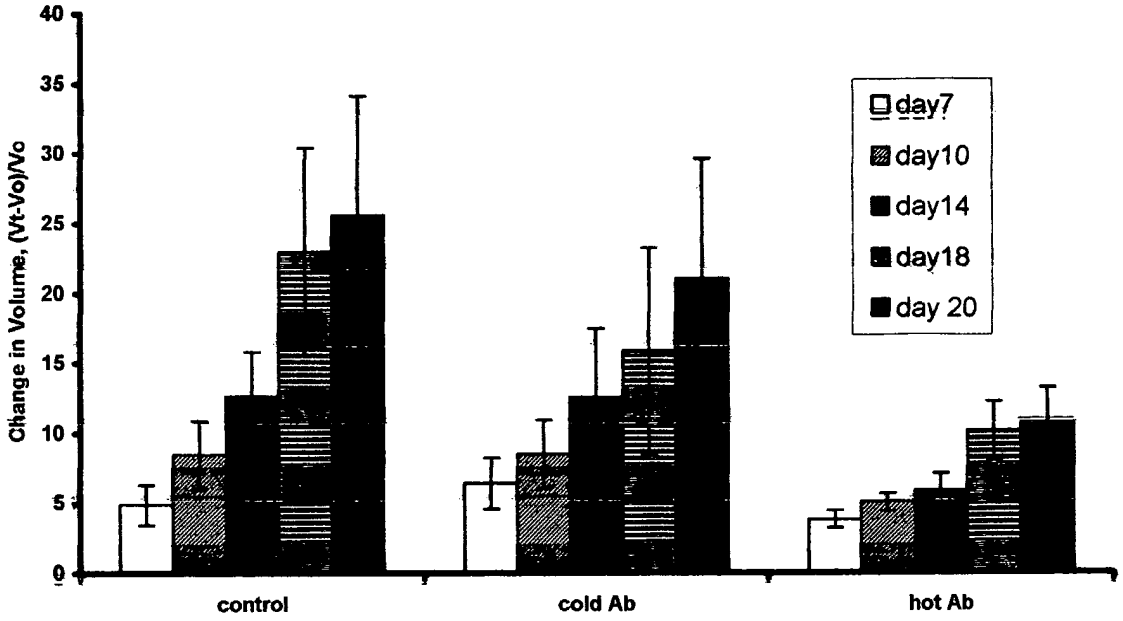
1. I am a co-inventor of the subject matter claimed in U.S. Patent Application No. 10/775,869. I am currently an Associate Professor in the Department of Nuclear Medicine and the Department of Microbiology & Immunology at Albert Einstein College of Medicine of Yeshiva University, Bronx, New York.

2. Described herein are additional data in support of the present invention, which were obtained *in vivo* with the anti-melanin monoclonal antibody 11B11 labeled with 188-Rhenium.

Monoclonal antibody (mAb) 11B11 was generated by immunizing BALB/c mice with purified *Cryptococcus neoformans* melanin followed by fusion of splenocytes to myeloma cells (Rosas AL, Nosanchuk JD, Feldmesser M, Cox GM, McDade HC, Casadevall A. Synthesis of polymerized melanin by *Cryptococcus neoformans* in infected rodents. *Infect. Immun.* 68(5):2845-53, 2000). The purified antibody was obtained from supernatant made by growing the 11B11 hybridoma cells in standard DMEM with 5% FCS. The antibody was captured on a column using agarose beads with anti-mouse IgM (Sigma) and eluted using acid then neutralized (pH 7). The antibody concentration was determined by ELISA by comparison to a commercial standard.

For radioimmunotherapy (RIT) studies, 12 week-old female nude mice were implanted subcutaneously with 8 x 10^6 A2058 human metastatic melanoma cells into the left flank and used for therapeutic experiments 12 days after tumors reached the size of approximately 0.15 cm^3 (0.02-0.4 cm^3). The mice were randomized into three groups of 5. The RIT group received IP 1 mCi dose of ^{188}Re-11B11 (100 μg) ("hot" mAb). The control groups received either 100 μg of unlabeled ("cold") 11B11 IP or PBS. 11B11 was radiolabeled with ^{188}Re "directly" as described in the present application. Mice were weighed and tumor volumes were measured immediately before administration of radiolabeled mAb and every 3-4 days thereafter. Tumors were measured in three dimensions with calipers, and tumor volume was calculated by multiplying the product of the three perpendicular diameters by 0.5, assuming an elliptical geometry.

The figure below presents the change in tumors volume with Vo being a tumor volume on the day of treatment, and Vt the tumor volume on the day of measurement. The study has demonstrated that radiolabeled 11B11 melanin-binding mAb is therapeutic in the highly aggressive and slightly melanized experimental human metastatic melanoma.



3. I hereby declare that all statements made herein and of my knowledge are true and that all statements made on information and belief are believed to be true; and I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Ekaterina Dadachova

Dated: Dec. 17, 2007